DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6005

January 9, 2001

WARNING LETTER

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

Mr. Anthony Calabro
President
Porfirio's Italian Food, Inc.
320 Anderson Street
Trenton, NJ 08611

File # 01-NWJ-15

Dear Mr. Calabro,

During a November 16, 2000 inspection of your firm located at the above address, an Investigator from this office documented serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your Crabmeat Ravioli product to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for your Crabmeat Ravioli product in that the hazard of Clostridium Botulinum is not controlled during the receiving of your canned pasteurized crabmeat. This observation, and need for correction, was also brought to your attention in a letter sent to you by this office on August 25, 1999.

2. You have not performed a hazard analysis to determine if a HACCP plan is required for the manufacture of your Shrimp Ravioli product.

3. You have no HACCP trained or qualified individual to develop HACCP plans for your seafood products. This observation was previously brought to your attention via the above referenced August 25, 1999 letter.

4. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(C)(4). However, your firm's HACCP plan for crabmeat ravioli does not monitor temperatures of pasteurized crabmeat upon receipt or storage prior to processing.

5. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm does not maintain sanitation monitoring records to document that monitoring is performed. This observation was also previously brought to your attention.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP regulations as well as Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and cosmetic Act and all applicable regulations.

Please send your reply to the Food and drug Administration, Attn: Joseph F. McGinnis R.Ph, Compliance Officer, at the address and telephone number listed above.

Sincerely,

Edward H. Wilkins, Acting for

Douglas I. Ellsworth
District Director
New Jersey District